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Hudson River HealthCare, Inc.

May 29, 2008

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Health Resources and Services Administration
Department of Health and Human Services
Attention: Ms. Andy Jordan
8C-26 Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857

**RE: Notice of Proposed Rulemaking - Designation of Medically Underserved Populations and Health Professional Shortage Areas – RIN 0906-AA44, 73 Federal Register 11232 *et. seq.* (February 29, 2008)**

To Whom It May Concern:

Hudson River HealthCare, Inc. (HRHCare) is pleased to respond to the above-cited solicitation from the Department of Health and Human Services (DHHS), Health Resources and Services Administration (HRSA) for comments on the proposed rule to revise and consolidate the criteria and the processes for designating Medically Underserved Areas and Medically Underserved Populations (MUAs and MUPs, respectively) and Health Professional Shortage Areas (HPSAs).

HRHCare's initial analysis of the Proposed Rule has revealed serious flaws in the proposed designation methodology, the specific criteria used, and the impact on safety-net health care services and on communities nationwide. Accordingly, HRHCare has serious misgivings regarding implementation of the Proposed Rule and **we believe that the magnitude of the concerns warrants withdrawal of the Proposed Rule and entry into a Negotiated Rule Making (NRM) to permit HRSA and relevant stakeholders to discuss and resolve such issues**. To ensure that there is no disruption in the operation of the current health care safety net, HRHCare also urges HRSA to suspend the review of any existing shortage designations until the Negotiated Rule Making is completed; this recommendation does not apply to new designation requests, which should continue to be processed as in the past. This concern, as well as our specific concerns regarding specific elements and provisions of the Proposed Rule, is discussed in greater detail below.

**Rationale:**
We are concerned that the Proposed Rule may not measure need accurately and fairly. Initial analysis of the Proposed Rule has identified concerns regarding the potential impact on New York State's Safety Net Health providers including Federally Qualified Health Centers and Look-A-Likes. We have reservations regarding the implementation

of the Proposed Rule and urge the withdrawal of the Proposed Rule and entry into a Negotiated Rule Making (NRM) process. This process would permit HRSA and relevant stakeholders (including NACHC, State Primary Care Associations and State Primary Care Offices, community organizations, health centers and other affected entities) the opportunity to discuss and resolve remaining issues arising from the Proposed Rule and subsequent modifications. In light of this request and to ensure there is no disruption in the operations of the health safety net in New York State, we also urge HRSA to suspend the review of all existing shortage designations until the Negotiated Rule Making is complete.

The comment time allotted was not adequate for the collection and analysis of relevant data. While we appreciate HRSA granting an extension of 30-days beyond the original comment period, New York still faced numerous barriers in conducting an accurate analysis within the relatively brief comment period. Because of the short time frame and the need for additional data, CHCANYS was unable to secure an analysis on Special Population Designations other than Medicaid Eligible. This means that the potential impact of the Proposed Regulations on Migrant Health, Healthcare for the Homeless Programs or any other "special populations" has not been assessed for New York State. We remain deeply concerned regarding the extremely brief duration of the comment period. In addition, only areas with current HPSAs and MUAs were analyzed to assess whether those may be lost. Estimates and assessments were not performed for areas that presently lack HPSAs and MUAs due to limited time and resources. 21

**Recommendation:**
**We request that HRSA revise the Proposed Rule and its preamble to include the clarification set forth in the recent Federal Register notice regarding the equal eligibility of all designations (Tier 1, Tier 2, and Safety Net Facility) to compete for new and additional resources.**

**Rationale:**
The implications of the new designations under the proposed rules are not well understood. Numerous state and federal programs use HPSAs and MUAs/Ps in the allocation of resources including funding under Section 330. However, it is not clear how the allocation of resources might change under the designation system outlined in the proposed rules. Consequently, while an impact analysis may be able to estimate the number of HPSAs and MUAs/Ps retained in New York, there is limited information on how that data may relate to the allocation of resources. Additionally, it is also unclear how scoring for homeless automatic designations and safety net facilities will compare to shortage area scoring. 16

While HRSA has clarified that Tier 1, Tier 2, and Safety Net Facility (SNF) designees are "equally eligible to compete for new or expanded funding," it remains unclear whether and to what extent there may be some prioritization of resources within and between

those categories. This raises additional questions, such as "How will priorities be assigned?" and "What will Tier 2 or SNF designation mean for those who are so designated?" Without clarification to how these new proposed designations will be implemented it is impossible to complete an analysis of the impact of the Proposed Regulations on New York State's health safety net providers.

**Recommendation:**
**We request that HRSA revise the Proposed Rule to explicitly clarify: (1) whether entities seeking Safety Net Facility designation must meet one or both of the proposed benchmarks; (2) that SCHIP and other public insurance coverage may count towards meeting the designation benchmark; and (3) that a Safety Net Facility designation only confers threshold eligibility to compete for affected federal resources, and that any ranking among competitors for such resources will be done as it is today – through the use of objective review and scoring of applications submitted by competitors.**

**We also requests that HRSA include any grantee that can show that they serve more than 60% of the population in their immediate area as a Safety Net Facility, and to include flexibility by permitting providers to utilize other benchmarks if sufficient justification exist and by including a process by which a provider can secure a "good cause" exception on a case-by-case basis.**

**Rationale:**
As noted above, the Proposed Rule provides for a new Safety Net Facility designation for facilities that meet certain thresholds. However, we have questions that require clarification to fully understand its impact of the SNF. For example, in meeting the requirements for SNF designation, it is unclear whether the entity must meet both:

- A threshold of at least 10% of their patients having been served under a sliding fee schedule or at no charge AND
- A certain percentage of total patients (based on whether the health center is located in a metropolitan, rural or frontier area) having been served under Medicaid, sliding fee schedule or at no charge
- Or whether meeting one threshold is sufficient

If both benchmarks, as opposed to only one of the two, must be met for Safety Net Facility designation, New York State and others states working to stem the problem of high numbers of uninsured, will be penalized for reducing the numbers of uninsured. Additionally, since SCHIP and other public insurance are indicators of health care need similar to Medicaid, all public insurance programs should be included in the benchmark needed for designation.

Given the scarcity of health care resources in frontier and rural areas, it is more likely that health centers located in those areas serve the entire community, caring for a wide cross section of patients by payor source and insurance status. The criteria governing eligibility for Safety Net facility designation status are not applicable in areas where the FQHC represents the major provider in the community. Any grantee that can show that they serve more than 60% of the population in their immediate area should, by definition, be considered a safety net provider. This information is readily accessible via the UDS service area analysis of users by zip code.

We also requests that HRSA revise the Proposed Rule to permit flexibility in satisfying threshold benchmarks for SNF designation by: (1) clarifying that only one of the benchmarks must be meet; (2) permitting providers to utilize other benchmarks if sufficient justification exists; and/or (3) including a process by which a provider can secure a —good cause exception on a case-by-case basis.

Finally, the recent Federal Register notice announcing the comment period extension indicated that HRSA plans to develop a new scoring methodology to rank relative need for Safety Net Facility designations for purposes of competing for NHSC placement (and which may be used to obtain other resources). The notice indicates that scores will take into consideration a host of factors that apply to the organization and its community as a whole, as well as the proportion of the health center's patients that meet the Safety Net Facility threshold benchmarks.

Given that the Safety Net Facility designation was created to ensure designation of facilities that meet certain thresholds of service to high-need populations, but that do not meet otherwise meet the requirements for area or population designation, using community-wide and organization-wide criteria appears to be inconsistent with the purpose and definition of the Safety Net Facility designation. Using such criteria to score and rank Safety Net Facility designations would effectively create a lower priority for Safety Net Facility designations, which ultimately is inconsistent with the stated intent that all designations will have equal access to compete for resources. Accordingly, we request that HRSA clarify that the designation process only confers threshold eligibility to compete for affected federal resources, and that any ranking among competitors for such resources will be done as it is today – through the use of objective review and scoring of applications submitted by competitors. In this way, HRSA will be assuring all affected entities that it will not create a lower priority for Safety Net Facility designations.

**Recommendation:**
**We urge HRSA to specify and define the important role played by relevant stakeholders, such as PCAs, local health departments, health centers, rural health clinics, NHSC sites and the impacted community itself, during the RSA determination process. And therefore request HRSA explicitly require within the**

**regulation (and not just the preamble) that states take into consideration input from such stakeholders prior to finalizing RSAs; and further, prior to approving a proposed alternative method, notice and comment must be provided to all relevant stakeholders.**

**Rationale:**
A key component of the proposed designation process is the identification of RSAs by each state. While the Proposed Rule permits service areas to be re-configured, it fails to address: (1) the manner by which states would manage this process (deferring instead to each state's plan); or (2) the extent to which relevant stakeholders and individual communities will have meaningful input into the process and/or flexibility to request modifications to state determinations from the federal government. The preamble to the Proposed Rule encourages states to develop statewide systems of RSAs with community input; however, the Proposed Rule itself does not explicitly require consultation with and input from stakeholders, including PCAs, local health departments, health centers, rural health clinics, NHSC sites and the impacted communities themselves. Further, the proposed rule explicitly requires input from "affected community officials/stakeholders" only if the state intends to define RSA parameters using criteria that differs from the broad and general RSA criteria specified in the proposed rule.

Additionally, as a result of merging the two methodologies (HPSA and MUA/P), states are required to "choose between" overlapping HPSAs and MUAs/Ps when identifying the boundaries of the RSA that will be considered for designation. Competing interests of different providers could greatly complicate these decisions. During the three-year transition period, HRSA will ask the state PCO to decide the boundaries of the RSA to consider for designation in instances where currently designated HPSAs and MUAs/Ps overlap. This process would potentially create tension between safety net providers that are not FQHCs and FQHCs in determining whether to maintain the HPSA boundaries or MUA/P boundaries. This is highly likely in the event that the MUA/P RSAs qualify for Tier 1 designations, while larger HPSA RSAs only qualify for special population designations.

**Additional Concerns and Overall Impact**

- **Currently designated primary care underserved areas in some parts of the New York State appear to be disadvantaged by the proposed methodology.** While some regions of the State may maintain existing designations under the proposed new rules, serious questions remain about other areas that exhibit problems with access despite the proposed rule. For example, the Western and Central regions in upstate New York could lose more than 30% of their currently designated HPSAs. Three currently designated whole county HPSAs in upstate areas failed to qualify under the proposed new rules. Of the eleven currently designated whole county HPSAs upstate

(8 geographic and 3 special population HPSAs), only seven qualified under the new rules, all as special population designations. One additional upstate county qualified under the proposed rules as a Tier 1 geographic designation. In addition, between 21% and 30% of MUAs/Ps in Central, Finger Lakes, and Hudson Valley regions fail to qualify for designation under the proposed new rules.

- **The contiguous area analysis requirement creates an uneven playing field for shortage area designations and could adversely impact either the number or type of designations in New York.** The proposed rules eliminate contiguous area analysis in states with a statewide system of RSAs. Consequently, there are likely to be more areas that qualify for higher level designations (e.g., geographic compared to special population) in states with a system of RSAs, regardless of whether or not primary care services are actually available in contiguous areas. In contrast, states without a statewide system of RSAs would be required to conduct contiguous area analyses for all proposed designations and, as a result, may see a reduction in the number of geographic designations or in the number of designations overall.

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- **Lack of data on the practice patterns of non-physician clinicians in New York is problematic.**
  This is the second time in ten years that HRSA has proposed shortage designation guidelines that include counting non-physician clinicians toward primary care capacity. New York State does not currently collect this data. New York will need to consider a strategy for collecting data on nurse practitioners, physician assistants, and midwives that better accounts for their contribution to primary care in the state.

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- **Using county-level health status data in sub-county analyses may mask health disparities and lower the 'designation scores' of underserved areas.** Much of the health status data available for New York City, for example, is at the county level or the neighborhood level. This makes it difficult to clearly describe significant problems related to health outcomes in high-need communities. Using county-level health outcome data could clearly result in lower designation scores for sub-county RSAs.

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- **An Appeal Process Should be Included**. While communities will be able to "appeal" a non-designation decision based on national data (*i.e.*, by submitting state/local data), we recommend revising the Proposed Rule to include a broader appeals process, which will permit appeals of other facets of the designation methodology (*i.e.*, structuring of rational service area definition; inclusion or exclusion of data related to special needs, *etc.*).

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- **Review of Existing Governors' Designations**. The Proposed Rule provides for review of all existing MUAs/HPSAs over a three-year period to determine whether they meet the new proposed methodologies. The recent Federal register notice announcing the extension of the comment period indicates that those existing designations which do not meet any of the new methodologies may still request a special "governor's designation" under the existing authority in Section 330(b)(3)(D). However, both the Proposed Rule and the recent Federal Register notice are silent regarding whether the existing governors' designations will be reviewed using the new proposed methodologies. As some New York State HPSAs and MUA/Ps have been granted "governor's designations" because the area/population in question did not meet current standards for designation, we recommend grandfathering existing governors' designations, thus avoiding unnecessary time and effort spent on re-requesting those special designations should the areas/populations continue to not meet one of the "regular" methodologies.

- **Update the Automatic Facility HPSA Language**. The Proposed Rule incorporates the current NHSC requirement that, 6 years from the date of automatic HPSA facility designation, the FQHC must demonstrate that it meets the then current designation rules to maintain the designation. Given that pending legislation in Congress may remove or adjust this time limitation from the NHSC statute, we recommend deleting it from the Proposed Rule.

- **Definition of "Medical Facility"**. The definition in § 5.2(i) of the Proposed Rule refers to the old FQHC definition set forth in Section 1861(aa)(4) of the Social Security Act, which excludes Health Care for the Homeless (HCH) programs. We suggest that HRSA revise this definition to match the current FQHC definition which removed the HCH exclusion. 12

We appreciate your attention in this matter and hope that you look favorably upon our comments.

Sincerely,

Anne Nolon
President & CEO